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Diplomate, American Board of Neurological Surgery

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket #97N-484S

Dear Sirs:

I wish to comment on the proposed FDA regulation of bone allografts as a medical device. I use bone bank supplies regularly in treating patients with spinal conditions requiring fusion. I do not think that this should be treated as a device since the bone banks which we are using to supply these products will have difficulty satisfying the FDA pre-market requirements such as sponsoring clinical trials and submitting regulatory documents..1 am very worried that this will restrict the supply of bone products upon which I rely on a daily basis.

I would therefore recommend that this proposed regulation not be accepted. I think I speak for many other physicians.

Sincerely,

Larry D. Tice, M.D.

LDT/sh

97N-484S

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